UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,181	12/09/2005	Gitte Juel Friis	P70948US0	1455

136 7590 01/21/2010

JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1619	

MAIL DATE	DELIVERY MODE
01/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,181	FRIIS ET AL.	
	Examiner	Art Unit	
	SHANON A. FOLEY	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-15,19,20,27,28 and 30-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-15,19,20,27,28 and 30-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 6, 7, 19, 20, 27, 28, 30, 32-35 **and new claims 36 and 37** are rejected under 35 U.S.C. 102(e) as being anticipated by Cleary et al. (USPgPub 2003/0170308).

Claim 36 requires that the pain relieving agent is below the daily unit dose for systemic treatment and claim 37 requires that the pain relieving agent is an anti-inflammatory pain-relieving agent.

Cleary et al. anticipate a wound care device that delivers active pain relieving agent of an NSAID or ibuprofen [see paragraph 0125] for local (non-systemic) [see paragraphs 0017, 0047, 0166] treatment of pain.

In response to the rejection of record, applicant argues that Cleary et al. teach that the maximum absorption in Table 6 is 0.223 g/ cm^2, which is higher than the claimed 0.2 g/ cm^2.

Applicant's argument and a review of Cleary et al. have been fully considered, but are found unpersuasive. The absorption value of Cleary et al. of 0.223 g/ cm^2 is equivalent to 0.2 g/ cm^2 since the values in the hundredths and thousandths positions are not significant enough for the tenths value of 0.2 to increase or mathematically rounded to 0.3. Therefore, it is maintained

that the absorption value taught by Cleary et al. in Table 6 metes the instantly required absorption value of 0.2 g/ cm^2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cleary et al. *supra* for reasons of record.

Applicant asserts that Cleary et al. do not teach decreased absorption means lower wound adhesion. Applicant points to paragraphs [0005 and 0146] as evidence that Clearly et al. teach "more absorbent" materials are "advantageous" because there is no risk of adhesion. Applicant's argument and a review of Cleary et al. have been fully considered, but are found unpersuasive since the teachings of Cleary et al. clearly teach wound devices with a low absorbency of 0.2 g/ cm^2, see Example 3 and line 4 of Table 6 on page 20. It is maintained that it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the wound-covering material with a reasonable expectation of success for altering the amount of absorbency required for adequate protection and healing.

Applicant also argues that the "topical" delivery routes of the analgesics in Clearly et al. is different from the instant invention, where the pain reliever is delivered directly to the wound.

Applicant's arguments have been fully considered, but are found unpersuasive because the active pain relieving agent of an NSAID or ibuprofen [see paragraph 0125] of Cleary et al. is

embedded or incorporated into a wound-contacting layer of hydrogel [see paragraphs 0119 and 0139] comprising nonstick petroleum resins [see paragraph 0065] that is suitable for permeability for wound exudates [see paragraphs 0018 and 0146]. Therefore, it is clear that the device of Cleary et al. also makes direct contact with the wound.

Claims 8-15 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cleary et al. *supra* and Edgren et al. (US 6,245,357) for reasons of record.

In response to this rejection, applicant argues that the Office does not provide any reason for motivation for combining the oral dosage form of Edgren et al. with the "patch-like" device of Cleary et al.

Applicant's arguments have been fully considered, but are found unpersuasive. The membrane system claimed by Edgren et al. in claim 28 is not limited to an oral dosage form. One of ordinary skill in the art at the time the invention was made would have been motivated to alter the quantity of analgesic drug released from a wound device, depending on the severity of the wound and the duration for pain relief required. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for altering the rate of analgesic release in the hydrogel of Cleary et al. in the membrane care system of Edgren et al. since both Cleary et al. and Edgren et al. deliver pain-relief agents through hydrogels, see the previous citations of Cleary et al. and claims 28 and 36-38 of Edgren et al.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANON A. FOLEY whose telephone number is (571)272-0898. The examiner can normally be reached on flex, generally M-F 7AM - 3 PM, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shanon A. Foley/
Primary Examiner
Art Unit 1619